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Larry Augsburg

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EXAMINER

SILVERMAN, ERIC E

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

10/15/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/749,339	Applicant(s) AUGSBURGER ET AL.	
	Examiner ERIC E. SILVERMAN	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 12-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7-18-2008</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' response filed 7/18/2008 has been received. Claims 1-38 are pending, claims 12-38 are withdrawn, and claims 1-11 are treated on the merits in this action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 recites the particles size of the cushioning component. The cushioning component need not be a bead or particle, and when it is not, it cannot have a particles size. Claims 3-4 are rejected for depending on claim 2 without rectifying this issue.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive. Applicants assert that the size in claim 2 should be read as the particle size of the placebo cushioning component bead or particle. Claim 1 requires that the "active cushioning component is a bead, granule, particle or pellet" but does not require that the placebo cushioning beads be in particulate form. The argument is not, therefore, persuasive.

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Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Mount et al., "Formulation and compaction of nonfracturing deformable coated beads", 1996 (IDS filed 7/18/2008).

Mount teaches a tablet dosage form made from compression of drug loaded beads and cushioning beads. Abstract, experimental section. The active loaded beads contain 10% drug (theophylline). Pellet manufacturing section. The placebo cushioning beads contain either wax alone (GPS) or a 1:1 combination of wax and microcrystalline cellulose (MCC), and are granulated in water. MCC is the "highly water-absorbing material" and GPS is the "highly-compactable filler" of claim 1. The active beads and cushioning beads are dried, mixed into a admixture, and tabletted. The recitation in claim 1 of the admixture being "freeze-dried" is a product by process limitation; in this case, the drying step in the art, while not freeze-drying, would produce an identical product (note that the claimed freeze drying step cannot remove all water, as water is a required component of the placebo cushioning component). Instant claims 2-4 are indefinite as discussed above, and the reference reads on them as they are best understood. The cushioning beads are used in amounts of 50%, 75%, or 90% with respect to the active bead (tableting section), reading on instant claims 5-7. The 1:1 ratio of GPS to MCC reads on the limitations of instant claims 8-10. Forming a tablet reads on instant claim 11.

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Claims 1-11 remain rejected under 35 U.S.C. 102(a) as being anticipated by Botzolakis for reasons of record and those discussed below.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive. Applicants' argue that the recited freeze drying step gives a product that is different from the oven-dried product of the art, in that the freeze drying gives the product unexpected cushioning capabilities. In response, it is noted that there is no evidence linking a freeze drying step to any cushioning ability. Indeed, the Mount reference (discussed above) teaches that effective cushioning can be obtained even without freeze drying (Mount does not freeze dry particles, but succeeds in obtaining a cushioning effect). After weighing the evidence of record, the proper conclusion is that the freeze drying step does not impart any material difference on the claimed product, and the rejection is therefore still proper.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Botzolakis in view of Habib.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive. Applicants' argue that the recited freeze drying step gives a product that is different from the oven-dried product of the art, in that the freeze drying gives the product unexpected cushioning capabilities. In response, it is noted that there is no evidence linking a freeze drying step to any cushioning ability. Indeed, the Mount reference (discussed above) teaches that effective cushioning can be obtained even without freeze drying (Mount does not freeze dry particles, but succeeds in obtaining a cushioning effect). After weighing the evidence of record, the proper conclusion is that the freeze drying step does not impart any material difference on the claimed product, and the rejection is therefore still proper.

Applicants then argue that the references do not teach freeze drying the active particles and the placebo cushioning component together. In response, it would be expected that mixing before drying, as in the claims, would produce the same product as if the two components were dried first and then mixed.

Applicants correctly note that Habib teaches that the means for preparation of the active loaded beads is not critical. This teaching of Habib is evidence that the products of the art, though they may be prepared by a slightly different method, are the same as those of the claims in all material aspects. There is no evidence to the contrary.

Claims 1-11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Habib in view of Botzolakis.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive.

Applicants' arguments are essentially identical to those presented against the rejection over Botzolakis in view of Habib, and are unpersuasive for the same reasons.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-11 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 16-30 of U.S. Patent No. 5,780,055 in view of US 4,910,023 to Botzolakis for reasons of record and those discussed above.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive.

Applicants arguments are essentially identical to those presented against the rejection

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under section 103(a) over Botzolakis and Habib, and are unpersuasive for the same reasons.

Conclusion

Applicant's submission of an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) on 7/18/2008 prompted the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 609.04(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ERIC E. SILVERMAN whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Eric E. Silverman
Art Unit 1618